

Applicant(s) : Shawn Shui-on Leung
U.S. Serial No.: 09/892,613
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REMARKS

Claims 40-49 were pending in this application. To fully address the issues raised by the Examiner in the December 15, 2006 Office Action, Applicant has amended the claims and specification accordingly. Applicant maintains that there is no issue of new matter, and urges the Examiner to enter this Amendment. Upon entry, claims 40-49 are pending and under examination.

Objection to the specification:

In the December 15, 2006 Office Action, page 4, the Examiner considered the replacement of "Rituxan" with "Rituximab" to be not persuasive, and suggested capitalizing the term "Rituximab". In response, Applicant has hereinabove replaced "Rituximab" with "RITUXIMAB".

Amendments to the specification:

Applicant respectfully calls the Examiner's attention to an obvious and unintentional mistake in the specification. Pages 26-28 of the specification teach the construction of the heavy chain variable region sequence by using oligonucleotides that encode amino acids of the VH region. Pages 28-30 of the specification teach the construction of the light chain variable region sequence by using oligonucleotides that encode amino acids of the VL region. Therefore, it would not make sense that the first, fourth, fifth and sixth paragraphs on page 29 of the specification should refer to the VH region in the middle of teaching about construction of the VL region. As such, the VH region referred to in these paragraphs should actually be the VL region. Accordingly, Applicant has hereinabove amended the specification to correct this obvious and unintentional mistake.

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Non-statutory obviousness-type double patenting:

In the December 15, 2006 Office Action, page 4, the Examiner maintained the provisional rejection of claims 40-49 on the ground of non-statutory obviousness-type double patenting. In response, Applicant respectfully requests that the provisional rejection be held in abeyance until the claims of the present application or the co-pending application no. 10/482,759 have been allowed.

Objection on the ground of inconsistency:

In the December 15, 2006 Office Action, page 4, the Examiner "suggested that claims 41-44 and 46-49 be amended to delete the term 're-engineered' for consistency" with claim 40. In response, Applicant has amended claims 41-44 and 46-49 accordingly.

Rejection for insufficient antecedent basis:

In the December 15, 2006 Office Action, page 5, the Examiner noted that "the parent immunoglobulin" in claim 40 and "said donor immunoglobulin sequences" in claim 45 lack sufficient antecedent basis.

In response, Applicant has amended claim 40, as suggested by the Examiner, to recite "A framework (FR)-patched immunoglobulin containing heavy and light chain variable region sequences from a parent antibody", and claim 45 to recite "one or more of said framework sequences from said human or primate immunoglobulins comprise one or more amino acids of the corresponding framework sequences from said parent immunoglobulin."

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Moreover, support for claim 45 can be found, *inter alia*, on page 16, lines 8-16; page 23, lines 27-33; page 32, lines 8-16; page 33, lines 12-15; and page 34, lines 8-15 of the specification.

Rejection under 35 U.S.C. 112, first paragraph:

In the December 15, 2006 Office Action, pages 5-6, the Examiner considered the proviso in claim 40 "that not all of the replaced FR1 . . . a single immunoglobulin light chain" to constitute new matter because "there is insufficient guidance and direction to the features" claimed in the proviso. Also, the Examiner elaborated on pages 7-8 of the Office Action that "there is insufficient written support for the limitation wherein the framework sequences are replaced by the corresponding framework sequences from a different immunoglobulin of the same species" as recited in claim 40.

In response, Applicant has amended claim 40 to fully address the above-mentioned concerns raised by the Examiner. Claim 40 is now in agreement with the Examiner's view, as described on page 8 of the Office Action, that "the specification only discloses FR-patching in the context of antibody humanization in which a non-human antibody (i.e., mouse antibody) is rendered less immunogenic in a human patient by replacing or patching each FR with a corresponding framework sequence from a human antibody". Since claims 41-49 are dependent upon claim 40, the amendment of claim 40 also addresses the same issue associated with claims 41-49.

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CONCLUSION

Applicant contends that the amendments have fully addressed the Examiner's objections and rejections indicated in the December 15, 2006 Office Action and should not raise additional issues. Therefore, this application is in full compliance with all requirements. Accordingly, Applicant respectfully urges the Examiner to place this application in condition for allowance.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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